

K921934 INTRADUCERJul 15, 1992
82 days to decisionK921934 · Product code: **GBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k921934/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Irrigation (GBX) |
| Date received | Apr 24, 1992 |
| Decision date | Jul 15, 1992 |
| Days to decision | 82 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Taut, Inc. |
| Location | Walker, MI, US |
| Contact | KENSETH |
| 510(k) history | 16 submissions · 16 cleared · 1983-2002 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k921934/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026